Appl. No.

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## AMENDMENTS TO THE CLAIMS

- (Original) A process for the expansions of TALL lymphocytes, wherein at least 1x10<sup>9</sup> cells are grown in homogeneous conditions in a single fermentation unit.
- (Original) The process as claimed in claim 1, wherein said fermentation unit is for anchorage dependent cells.
- (Original) The process as claimed in claim 1, wherein said fermentation unit is a multi-chamber stack.
- 4. (Original) The process as claimed in claim 3, wherein said fermentation unit is a Cell-Factory $^{TM}$ .
- (Currently amended) The process as claimed in claim 3, wherein the expansion
  in the homogeneous system is preceded by a process of pre expansion in flask until obtaining a
  number of cells comprised from 0.7 to 1x10<sup>8</sup>.
- 6. (Original) The process as claimed in claim 5, wherein the cellular density of the inoculum is at least  $0.7x10^6$  cells/ml and is preferably equal to  $0.75x10^6$  cells/ml and, at the harvest time, the density is lower than  $2x10^6$  cells/ml, preferably than  $1x10^6$ .
- 7. (Original) The process as claimed in claim 4, wherein the Cell-Factory<sup>TM</sup> is a 10-chamber unit.
- (Original) The process as claimed in claim 1, wherein TALL lymphocytes are selected from the group consisting of: TALL-104, TALL-107, TALL-103/2 cell lines, optionally genetically modified.
- (Currently amended) Process according to claim 6 8 wherein TALL are TALL-104 lymphocytes, optionally genetically modified.
- 10. (Previously presented) The process as claimed in Claim 1, wherein the complete culture medium in the cell-factory amplification phase also comprises 10% maximum human serum, preferably in the range of 4 to 6%, still more preferably of 5%, and interleukin in a concentration comprised from 80 to 120 IU/ml.
- (Original) The process as claimed in claim 10, wherein interleukin-2 is added to the cell culture every 48-90 hrs.
- (Original) The process as claimed in claim 10, wherein the cell growth in the homogeneous system takes place in an antibiotic-free culture medium.

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 (Currently amended) A process for the preparation of frozen bags of TALL lymphocytes in an amount of at least 1x10° cells, comprising using eharacterized in that it eomprises the process according to Claim 1.

- 14. (Previously presented) The process as claimed in claim 13, wherein the bag is sealed transversally to the bag filling collet at least in two points to create at least a sampling chamber containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.
- 15. (Currently amended) A process for the preparation of a therapeutic dose of at least 1x10<sup>9</sup> TALL lymphocytes in a homogeneous culture comprising using characterized in the fact it comprises the process according to Claim 1.
- (Currently amended) The process as claimed in claim <u>13</u> 45, wherein the lymphocytes are TALL-104.
- 17. (Withdrawn) TALL lymphocytes obtainable according to the process of Claim 1 wherein said lymphocytes are characterised by a CD3<sup>+</sup> and CD8<sup>+</sup> immunologic markers expression of 98% min, preferably ≥99%, and by the CD56<sup>+</sup> marker expression of 95% at least, preferably ≥97%.
- 18. (Withdrawn) TALL lymphocytes according to claim 17 characterised by a biological activity, determined by a cytotoxicity assay on appropriate target cells, equal to at least 70% of the control.
- 19. (Currently amended) Process The process according to claim § 6 wherein TALL lymphocytes are TALL-104 lymphocytes.
- 20. (Currently amended) The process as claimed in Claim 9 19, wherein the complete culture medium in the cell-factory amplification phase also comprises 10% maximum human serum, preferably in the range of 4 to 6%, still more preferably of 5%, and interleukin in a concentration comprised from 80 to 120 IU/ml.
- (Currently amended) A process for the preparation of frozen bags of TALL lymphocytes in an amount of at least 1x10° cells, comprising using eharacterized in that it comprises the process according to Claim 9.19.
- 22. (Previously presented) The process as claimed in claim 21, wherein the bag is sealed transversally to the bag filling collet at least in two points to create at least a sampling

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chamber containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.

- 23. (Currently amended) The process for the preparation of a therapeutic dose of at least 1x10<sup>9</sup> TALL lymphocytes in a homogeneous culture eharaeterized in the fact it comprises comprising using the process according to Claim 20.
- 24. (Withdrawn) TALL lymphocytes obtainable according to the process of Claim 20 wherein said lymphocytes are characterised by a CD3\* and CD8\* immunologic markers expression of 98% min, preferably ≥99%, and by the CD56\* marker expression of 95% at least, preferably ≥97%.